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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,233	02/28/2002	Maria Alexandra Glucksmann	MPI01-021P1RNM	6932

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MILLENNIUM PHARMACEUTICALS, INC.
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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,233	GLUCKSMANN, MARIA ALEXANDRA	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *29 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,29 and 32-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,29 and 32-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed 3/29/06 has been entered. The Declaration of Timothy D. Ocain filed under 37 CFR 1.132 has been entered.

2. IDS file 7/9/02, 4/8/03 and 6/23/05 have been considered.

3. **Objections**

The disclosure remains objected to because of the following informalities: The specification remains objected to for use of hyperlinks, for example, page 7, paragraph 28. The specification should be reviewed for improper recitation of hyperlinks. All such recitations should be deleted or amended such that the hyperlinks are rendered inactive. See MPEP 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 29, and 37-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is remains indefinite because it is not clear what is "93870-mediated signal transduction" and how the detection of binding of a test compound to the polypeptide is determined by "an assay for 93870-mediated

signal transduction". Applicant's arguments have been fully considered but are not found persuasive. The assay for 93870-mediated signal transduction fails to show when the test compound has bound to the polypeptide. The 93870-mediated signal transduction pathway is not disclosed in the specification. The ligand for 93870 polypeptide nor its associated G protein (Gs, Gi or Gq) are disclosed. The second messenger for 93870-mediated signal transduction nor the metes and bounds of the signal transduction pathway effected by 93870 polypeptide stimulation are disclosed. Therefore, without knowledge of the 93870-mediated signal transduction pathway the metes and bound of the claim cannot be determined. For example what activity of the 93870-mediated signal transduction indicates that a test compound binds the polypeptide?

Claims 40, 41 are also rejected for use of "93870-mediated signal transduction" for the reasons given above

Claim 41 remains indefinite because it is not clear what is "mobilization of a molecule" in the context as used in the claim and what aspect of said mobilization shows that the test compound has bound to the polypeptide. Applicant's arguments have been fully considered but are not found persuasive. The specification does not provide a definition of "mobilization of a molecule" so that it discloses test compound has bound to 93870-polypeptide. Mobilization means the act of mobilizing or state of being mobilized. Mobile can mean capable of moving or being moved, changeable in appearance, mood or purpose. It is not clear what capability of being mobile indicates that a test compound has bound to the polypeptide. If applicant is wishing to claim, for

example mobilization as metabolism of phosphatidylinisitol4, 5-bisphospahte then the claim should be amended appropriately. Without knowledge of the specific "93870-mediated signal transduction" it not clear how the molecule is mobilized so as to allow the metes and bounds of the claim to be determined.

Claims 37-39 and 42 are rejected for depending upon an indefinite base (or intermediate) claim and fail to resolve the issues raised above.

Claim Rejections - 35 USC 101 and 35 USC 112, 1st paragraph

The following is a quotation of 35 U.S.C. 101:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 28-29 and 32-43 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for reasons of record in the previous Office

action and for those given below. Applicant's arguments and the Declaration of Timothy D. Ocain have been fully considered and are addressed below.

Applicant agues that the polypeptide of SEQ ID NO:2 is a GPCR. Applicant's arguments are found persuasive. Applicant further argues the skilled artisan could readily envision cellular responses to the activity of SEQ ID NO. 2. In this regards Applicant's arguments are not found persuasive. The polypeptide of SEQ ID NO:2, although belonging to the general family of GPCRs is an orphan GPCR. As disclosed in the previous Office action members of a sub-family of G-protein-coupled receptors are also highly divergent in their effects, as highlighted by Murdoch et al (Blood, Volume 95, No.10, pages 3032-3043, 2000). The utility of claimed receptor cannot be implicated solely from homology to known G-protein coupled receptors or their protein domains because the art does not provide teaching stating that all members of family of G-protein coupled receptors must have the same effects, the same ligands and be involved in the same disease states, the art discloses evidence to the contrary. The specification has not even used protein domains/homology to predict the activity of the protein. Murdoch discloses the superfamily of G-protein-coupled receptors are highly divergent in their effects and include receptors for hormones, neurotransmitters, paracrine substances, inflammatory mediators, certain proteinases, taste and odorant molecules, and even photons and calcium ions. The specification does not disclose the ligand that modulates 93870 polypeptide activity or the physiological function of said polypeptide.

Applicant further argues that a utility to an orphan receptor can be assigned with knowledge of what disease is associated with the claimed receptor or what drugs/ligands effect a specific receptor function. Examiner agrees that if a specific association of 93870 polypeptide with a disease state was a was known at the time of filing instant application that information would be enough to overcome the utility rejection. Further the Examiner agrees that if 93870 polypeptide, at time of filing of instant application, had known specific drug/ligand interactions that resulted in a modulation of a physiological function that too could be used to argue utility and possibly overcome the utility rejections of record. Unfortunately, at time of filing of instant application, neither the disease state nor the drug/ligand interactions were known as they pertain to 93870 polypeptide. Applicant argues the Declaration of Dr. Ocain in which the data compiled and presented to Dr. Ocain by Dr. Ethan Grant is discussed is sufficient to overcome the utility rejection. Applicant's arguments and the Declaration of Timothy D. Ocain have been fully considered and are addressed below. The data presented is post filing art in which an attempt was made to deorphanize the receptor, an act of further experimentation on a receptor whose functionality and ligand properties were unknown to Applicant at time of filing of instant application. The specification pages 15, 16 and 17 discloses 93870 molecules and modulators thereof can act as therapeutic agents for controlling one or more of GPCR associated disorders selected from a laundry list of over 200 unrelated disorders. The disclosed disorders have no common nexus or common etiology and range in spectrum from alcohol toxicity, vaginitis, diabetes, leprosy to encompassing

involvement with every carcinoma. Based on the specification Applicant went on a fishing expedition to find a ligand for 93870 polypeptide and/or determine a correlation of 93870 polypeptide with a cellular dysfunction. Applicant's arguments and the Declaration argue a utility for the 93870 polypeptide as having a role in immune and inflammatory disease, including arthritis, inflammatory bowel disease and potentially chronic obstructive pulmonary disease. Applicants argue 93870 polypeptide can be used in the diagnosis and prognosis of the disease or in screening assays. Applicant's assertion of utility is based on the data provided in the declaration which states:

1. Expression is highest in monocytes, macrophages and granulocytes. Expression was detected in most RA tissues, showing a pattern similar to that observed for the control gene CD68, consistent with expression of the target in tissue macrophages and/or granulocytes. Expression is unregulated in both CIA and ABIA models of arthritis.

2. Higher expression was detected in human UC tissues compared to normal colons and in a mouse model of IBD. Little to no expression was detected in normal or COPD lung tissue, though the expression in monocytes, macrophages and activated NHBE cells makes the gene of interest for further analyses of human COPD and mouse model tissues when additional reagents become available

Applicants also argue the *in vivo* data also show a progression of increasing 93870 expression which correlates with disease severity in an arthritis animal.

Applicant's arguments and the Declaration of Timothy D. Ocain have been fully considered and are addressed below. First, the post filing data provided in the declaration cannot be used to provide utility for the claimed invention because said data was not known at the time of filing of instant application. Based on the laundry list of possible diseases associated with 93870 polypeptide further experimentation, at the time of filing, was required to determine the functionality of 93870 polypeptide and in turn its utility in claimed method. Further the specification, page 15, first paragraph, states, "93870 molecules and modulators thereof can act as novel therapeutic agents for controlling **one or more** of GPCR associated disorders", selected from a laundry list of diseases. The assertion of the association of 93870 molecules and modulators thereof with "one or more" GPCR associated disorders does not automatically lead to concluding its role in arthritis or inflammatory bowel disease, even with the greatest leap of faith by the skilled artisan. That conclusion can only be reached by further experimentation, therefore Applicant's invention lacks utility. Even if Applicant's data presented in the Declaration was applicable to assign utility, the data presented showing increased expression in many tissues of different disease model animals does not disclose the specific role of the 93870 polypeptide in a specific disease state. For example is the upregulation of 93870 polypeptide a cause or an effect of the dysfunction present in the animal model. If the upregulation of 93870 polypeptide is due to effect of the dysfunction then 93870 polypeptide's ligand binding properties may have no effect on the disease.

What is the function of a ligand that binds 93870 polypeptide? Is it beneficial in treating a specific dysfunction or is it detrimental?

Based on the record, there is not a "well established utility" for the claimed invention. It noted that neither the specific activity of GPCR of SEQ ID NO:2 or the specific treatable disease associated with the GPCR of SEQ ID NO:2 is disclosed in the specification. There is no disclosure of the specific activity of claimed GPCR. There is no disclosure of how to specifically use the compound identified by claimed method. Further no ligands that bind or activate said GPCR are disclosed. In light of the specification the skilled artisan cannot come to any conclusions as to the function of the 93870 polypeptide G protein-coupled receptor of SEQ ID NO:2. The utility of claimed 93870 polypeptide cannot be implicated solely from homology to the proteins known in the art because the art does not provide teaching stating that all protein disclosed have the same activity, same effects, the same ligands and are involved in the same disease states (discussed later). In light of the specification and art the skilled artisan cannot come to any conclusions as to the function of protein of instant invention. There is no disclosure provided within the instant specification on what specific function the protein of SEQ ID NO:2 possesses, or how to use compounds that bind said protein. No specific disease states are disclosed that are directly related to 93870 polypeptide dysfunction. A laundry list of dysfunctions that **may** be related to a disease state are disclosed.

The specification fails to disclose, what disease is associated with claimed receptor dysfunction or what drugs effect a specific claimed receptor function.

The GPCR may have utility in the future, when it has been further characterized (e.g. its dysfunction or function correlated with a disease state) and its ligand characterized. The inclusion in the family of G protein coupled receptors (GPCR) does not constitute either a specific and substantial asserted utility or a well established utility for that particular GPCR or protein. This is analogous to all proteins or GPCRs can be used as protein markers on a gel.

Specification discloses claimed receptors are useful in screening but the specification does not disclose what claimed receptor specifically regulates and what specific disease the receptor is a target for. What would be the use of using the claimed receptor on a panel for drug screening? The receptor has no known ligand or known function. How would one use the compounds that interacted with said orphan receptors? The specification provides a diverse list of disease states that may be involved in receptor dysfunction. It is unpredictable what ligands will bind to orphan receptors, and further the functional effects of ligand binding may remain uncertain even after extensive experimentation. The ordinary artisan can only speculate on the utility for the ligand and receptor. A utility to orphan receptor cannot be assigned without knowledge of what disease is associated with claimed receptor dysfunction or what drugs/ligands effect a specific claimed receptor function.

It can be argued the GPCR of SEQ ID NO:2 is useful tool as a reagent or a molecular target in the diagnosis and treatment of GPCR mediated disorders. All members of the GPCR protein family have a utility in selectively screening of candidate drugs that target GPCRs. However, for a utility to be well-established

it must be specific, substantial and credible. In this case, as all receptors are in some combination useful in selectively screening of candidate drugs that target GPCRs. However, the particulars of screening of candidate drugs, that target GPCR of SEQ ID NO:2, are not disclosed in the instant specification. The candidate drugs nor the susceptible organ systems are identified. Therefore, this is a utility, which would apply to virtually every member of a general class of materials, such as any collection of proteins or DNA, but is only potential with respect to GPCR of SEQ ID NO:2. Because of this, such a utility is not specific and does not constitute a well-established utility. Further, because any potential diagnostic utility is not yet known and has not yet been disclosed, the utility is not substantial because it is not currently available in practical form. Moreover, use of the claimed protein for screening compounds that are a target for GPCR of SEQ ID NO:2 is only useful in the sense that the information that is gained from the assay and is dependent on the effect it has on the protein, and says nothing with regard to each individual member of the GPCR family. Again, this is a utility, which would apply to virtually ever member of a general class of materials, such as any collection of proteins or DNA. Even if the expression of Applicants individual GPCR is affected by a test compound in an assay for drug screening, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. Given this consideration, the individually claimed method of using claimed GPCR has no well-established use. The artisan is required to perform further experimentation on the claimed GPCR itself

in order to determine to what use any information regarding this protein could be put.

Congress intended that no patent be granted on a chemical compound whose sole utility consists of its potential role as an object of use-testing. *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. 101.

Further, GPCR of SEQ ID NO:2 belongs is a family in which the members have divergent functions based on which tissues the protein is expressed or administered to. Assignment to this family does not support an inference of utility because the members are not known to share a common utility. There are some protein families for which assignment of a new protein in that family would convey a specific, substantial and credible utility to that protein. For example, some families of enzymes such as proteases, ligases, telomerases, etc. share activities due to the particular specific biochemical characteristics of the members of the protein family such as non-specific substrate requirements, that are reasonably imputed to isolated compositions of any member of the family. The diversity of the GPCRs has already been described. Without some common biological activity for the family members, a new member would not have a specific or substantial utility when relying only on the fact that it has structural similarity to the other family members. The members of the family have different biological activities, which may be related to tissue distribution, but there is no evidence that the claimed compounds share any one of diverse number of activities. That is, no activity is known to be common to all members.

To argue that all the members can be used for drug screening, toxicology testing and diagnosis, is to argue a general, nonspecific utility that would apply to virtually every member of the family, contrary to the evidence. Further, any compound could be considered as a regulator or modulator of tissue in that any compound, if administered in the proper amount, will stimulate or inhibit tissue. For example, salt, ethanol, and water are all compounds which will kill cells if administered in a great enough amount, and which would stimulate cells from which these compounds had been withheld, therefore, they could be considered regulators or modulators of tissue. However, use of these compounds for the modulation of tissue would not be considered a specific and substantial utility unless there was some disclosure of, for example, a specific and particular combination of compound/composition and application of such in some particular environment of use.

Without knowing a biological significance of the claimed GPCR, one of ordinary skill in the art would not know how to use the claimed invention in its currently available form in a credible real world manner based on the diversity of biological activities possessed by the GPCR family. Contrast *Brenner*, 148 USPQ at 694 (despite similarity with adjacent homologue, there was insufficient likelihood that the steroid would have similar tumor-inhibiting characteristics), with *In re Folkers*, 145 USPQ 390, 393 (CCPA 1965) (some uses can be immediately inferred from a recital of certain properties) or *In re Brana*, 34 USPQ 1436, 1441 (Fed. Cir. 1995) (evidence of success in structurally similar compounds is relevant in determining whether one skilled in the art would believe

an asserted utility; here, an implicit assertion of a tumor target was sufficiently specific to satisfy the threshold utility requirement).

The assertion that the claimed invention has utility in drug screening, drug development and disease diagnosis, do not meet the standards for a specific, substantial or well-established utility for reasons set forth above. None of the utilities identified have been demonstrated to be specific to the polypeptide of SEQ ID NO:2 . One of ordinary skill in the art must understand how to achieve an immediate and practical benefit from the claimed species based on the knowledge of the class. However, no practical benefit has been shown for the use of the polypeptide SEQ ID NO:2. Applicant has failed with respect to GPCR of SEQ ID NO:2, has not described the family of GPCRs in enough detail to show, by a preponderance of the evidence, that the polypeptide of SEQ ID NO:2 has any substantial use. The record shows that the family of proteins having GPCR domains is diverse, and has such a broad definition, that a common utility cannot be defined. Moreover, the evidence of record is inadequate to determine the disease(s), drug(s) or toxicological screen(s) for which the compounds would be useful. In *Brenner,* the Court approved a rejection for failure to disclose any utility for a compound where the compound was undergoing screening for possible tumor-inhibiting effects and an adjacent homologue of the compound had proven effective. *Brenner*, 148 USPQ at 690. Here, there is no evidence that the claimed isolated compounds have any utility.

For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention.

The use of the claimed invention for assay development, drug discovery, and disease diagnosis are not substantial utilities. The question at issue is whether or not the broad general assertion that the GPCR of SEQ ID NO:2 might be used for some diagnostic application in the absence of a disclosure of which diagnostic application would be considered to be an assertion of a specific, substantial, and credible utility. For reasons set forth above the disclosure satisfies none of the three criteria *See In re Kirk*, 153 USPQ 48, 53 (CCPA 1967) (quoting the Board of Patent Appeals, We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.)

The prior rejection under 101 followed *Brenner v. Manson*. In that case, the absence of a demonstrated specific utility for the claimed steroid compound was not ameliorated by the existence of a demonstrated general utility for the class. Unlike *Fujikawa v. Wattanasin*, where there were pharmaceutically acceptable in vitro results, here, there is nothing other than relatively low levels of sequence homology to a broad and diverse family of proteins having distinct modes of activity, and no disclosed common mode of action. A rejection under 112, first

paragraph, may be affirmed on the same basis as a lack of utility rejection under 101. *See, e.g., In re Swartz*, 56 USPQ2d 1703 (Fed. Cir. 2000); *In re Kirk*, 153 USPQ 48 (CCPA 1967). Further since the claimed GPCR has no utility, methods of its use are also rejected for lack of utility.

6. Claims 28-29 and 32-43 remain rejected under 35 U.S.C. 112, first paragraph for the reason given below and those disclosed in the previous office action. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Since neither the specification nor the art of record disclose any activities or properties that would constitute a real world context of use for the method of identifying compounds that bind the GPCR of SEQ ID NO:2, further experimentation is necessary to attribute a utility to the GPCR of SEQ ID NO:2 and methods of using said receptor in screening agents as possible therapeutics. The claims fail to disclose how to use the claimed invention for the reasons given above (lack of utility). Further the claims are drawn to an orphan GPCR whose activity, physiological function associated G-protein and activating ligands were not known at the time of filing of instant application. Neither the claims nor the specification disclose what specific biological activity is associated with the GPCR of SEQ ID NO:2. There is no disclosure of the specific compounds that are activated in the signal transduction pathway or what ligand is

capable of binding to the GPCR of SEQ ID NO:2, so as to disclose a specific function for said GPCR. There is no disclosure of how to assay activity since the natural ligand and function of GPCR of SEQ ID NO:2 is unknown.

Applicants argue as evidenced by publication such as Wilson et al one of skill in the art did not require a ligand to use an orphan GPCR. Applicant's arguments and the Declaration filed 3/29/06 have been fully considered but are not found persuasive. In instant application where the receptor is an "orphan" and has no disclosed physiological function it lacks utility and enablement for the reasons given above.

The complex nature of GPCRs and the unpredictability of assigning a function to a receptor with no known ligand or function is described in the rejection under 35 USC 101 and 35 USC 112, 1st paragraph, see the teachings of Murdoch, Watson, Kenakin, Karp and Bork (disclosed in previous office action).

Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation. Further for an agent to be a candidate therapeutic agent, the dysfunction associated with the GPCR of SEQ ID NO:2 must be known. In instant case it is not known what dysfunction is associated with the GPCR of SEQ ID NO:2. The question is even if a an agent does bind to with the GPCR of SEQ ID NO:2 or regulates its

expression, then what? Applicant still has to find a therapeutic use of said agent. The activity regulated by the GPCR of SEQ ID NO:2 is unknown.

7. No claim is allowed

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nirmal S. Basi
Art Unit 1646
June 9,2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER